Standard Operating Procedure –

Release and Distribution of Standard Operating Procedures the caBIG™ Program

This cover sheet controls the layout and components of the entire document.

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Effective Date: 10/31/2005

Department Approval:

Sue Dubman

NCICB Applications Director

QA Approval:

Brenda Duggan

Acting NCICB QA Officer

Note: This document will be issued for training on the Issue Date. The document will become available for use to trained personnel on the Effective Date. Before using this document, make sure it is the latest revision. Access the caBIG™ website to verify the current revision.

Revision History

Revision	Date	Author	Change Reference	Reason for Change
1.0	09/19/2005	SOP Working Group	N/A	Initial release.

1. Purpose

This Standard Operating Procedure (SOP) describes the process for the release and distribution of SOPs developed by the National Cancer Institute Center for Bioinformatics (NCICB) for use at intramural and extramural sites under the caBIG™ Program.

2. Scope

This SOP will be used as guidance for the approval, release and distribution of all SOPs developed by NCICB related to: a) research covered under the caBIG™ Program and sponsored by the National Cancer Institute (NCI) and, b) the sharing of data across caBIG™ participant sites, the regulatory community and commercial industry.

3. Requirements

3.1 All SOPs will be developed, maintained, and updated in compliance with the *SOP for SOPs* and *SOP for Revisions and Deviations* approved by the NCICB and the SOP Working Group.

3.2 All SOPs will be reviewed and signed off by the NCICB Applications Director, and the appropriate NCICB QA applications representative.

3.3 All SOPs will be assigned a version number, issue date (the date the SOP becomes available for training) and an effective date (the date the SOP becomes operational). The effective date will be at least three weeks after issue date to allow time for training on the new or revised SOPs.

3.4 Participating sites under caBIG™ will maintain a local repository for SOPs to contain approved SOPs and any additional or modified Procedures.

3.5 Before an SOP becomes effective the SOP shall be made available to all participating sites and training shall be completed for all appropriate staff.

3.6 SOPs will be published on the caBIG™ website in PDF format to prevent unauthorized changes to the published document.

3.7 SOPs will be placed under version management control to prevent unauthorized changes to the approved SOP baseline. If paper signatures are used, NCICB will maintain the original signed paper documents.

4. References/Regulations/Guidelines

Section	SOP Number	Title
4.1	N/A	CDISC Glossary
4.2	AD-001	SOP for Develop and Maintain SOPs
4.3	AD-002	SOP for Managing Deviations and Revisions to SOPs
4.4	N/A	International Conference on Harmonization; Good Clinical Practice Guidelines, E6, Section 1.55
4.5	N/A	21 CFR 312.60 General Responsibilities of Investigators

5. Roles & Responsibilities

Role	Responsibility
Author	• Create SOP and procedures per SOP for SOPs and SOP for Deviations. • Submit SOP for review and approval by the SOP Working Group. • Work with the Document Office to assign the version number and issue date.
NCICB QA Officer	• Ensure SOP numbering system is consistent and in specified format. • Review final SOP for Quality Control of SOP formatting. • Responsible for approving all SOPs. • Maintain a record of final approval dates and versions. • Sign-Off on SOP – indicating that the SOP complies with NCI policy, and applicable SOPs for creating and maintaining SOPs.
SOP Working Group	• Review and Approve final draft of SOP.
NCICB Applications Director	• Sign-Off on SOP – indicating that the NCICB and the SOP Working Group has approved the SOP.
Technical Officer	• Upload approved SOPs onto caBIG™ website. • Provide troubleshooting support for accessing and downloading approved SOPs.
Document Officer	• Notify all caBIG™ users of new SOP posting. • Manage SOPs including version control, effective dates and establishing methods to organize SOPs for easy access.
Participating Sites	• Ensure that all necessary training for SOP is provided and completed prior to SOP becoming operational. • Maintain effective SOPs in a local repository.

6. Attachments

This SOP will be used in conjunction with the following attachments. These attachments must be used by all research sites conducting clinical trials under the caBIG™ Program and can be customized by individual research sites to accommodate format and content in accordance with local guidelines and/or requirements.

Title	Description
1) Procedure Description for Release and Distribution of SOPs	This document provides instructions for the approval, release and distribution of SOPs and it establishes procedures and responsibilities to ensure that all SOPs are made available to users in a consistent manner. The content of this procedure should be followed strictly; any departure from this procedure should be documented and brought to the attention of senior clinical staff at the site.
2) Procedure Description for Numbering and Versioning of SOPs	This document provides guidance for the numbering of SOPs. This procedure also documents the versioning process for SOPs.
3) Process Flow for Release and Distribution of SOPs	This document graphically depicts the work flow activities, by role, that are performed in the process for releasing and distributing SOPs.